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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
nB. 12/23/91

IN RE APPLICATION OF	
THOMAS F. DEUEL, YUE-SHENG LI, NED R. SIEGEL AND PETER G. MILNER	GROUP ART UNIT: 1812
SERIAL NUMBER: 07/542,232	EXAMINER: SHELLY GUEST
FILED: JUNE 21, 1990	
TITLE: HEPARIN-BINDING GROWTH FACTOR	

PETITION TO THE COMMISSIONER FROM
REQUIREMENT FOR RESTRICTION
UNDER 37 CFR §1.144

Hon. Commissioner of Patents and Trademarks

Washington, D. C. 20231

DEC 2 1991 REGISTERED

Dear Sir:

Applicant herewith petitions the Commissioner to reverse the requirement for restriction which was made final in the above-identified application.

P 30610 06/09/92 07542232 13-4125 030 125 120.00CR

Please charge the deposit account no. 13-4125 of Monsanto Company, who is handling the prosecution of this application, in the amount of $120 to cover the cost of this petition. Duplicate copies of a Deposit Account Order form PTO-140 to cover this charge are attached hereto. Any deficiency or overpayment should be charged or credited to this deposit account.

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Attorney for Applicants 11/15/91
Date

Registration No. 25,275

REMARKS

In the office action mailed May 24, 1991, Paper No. 5, restriction was required under 35 U.S.C. §121 to one of the following two inventions:

I. Claims 1-3, drawn to a protein growth factor, classified in Class 530, subclass 399.

II. Claims 4-7, drawn to a DNA encoding a growth factor, classified in class 536, subclass 27.

Applicant traversed the requirement for restriction but provisionally elected to prosecute the invention of Group II, Claims 4-7, in Amendment A, filed August 22, 1991, Paper No. 6.

The requirement for restriction was made final by the Examiner in the final rejection mailed October 28, 1991, Paper No. 7.

The requirement for restriction should be reversed for the following reasons:

A. THE RESTRICTION REQUIREMENT AS BETWEEN INVENTIONS I AND II IS IMPROPER BECAUSE THE INVENTIONS ARE NOT INDEPENDENT AND DISTINCT AS SPECIFIED BY MPEP §803

Under the provisions of MPEP §803, restriction is not proper if the inventions are not independent and distinct.

A careful review of Claim 2 of the Group I invention and Claim 4 of the Group II invention will reveal that both claims recite the identical amino acid sequence of a 168 residue protein. Likewise, a careful review of Claim 3 of the Group I invention and Claim 6 of the Group II invention will reveal that both claims recite the identical amino acid sequence of another 168 residue protein. Thus, the DNAs of the Group II claims necessarily involve the protein sequences of the Group I claims. That is, the Group I and II claims are not independent and distinct but, instead, are intimately and inextricably related to each other. Accordingly, the requirements of MPEP §803 concerning independent and distinct inventions have not been satisfied by the Examiner.

B. THE CONCLUSIONS STATED BY THE EXAMINER FOR THE RESTRICTION REQUIREMENT ARE NOT SUPPORTED BY VALID OR SUFFICIENT REASONS AS SPECIFIED BY MPEP §803

Under the provisions of MPEP §803, the Examiner must provide reasons and/or examples to support the conclusions for the restriction requirement.

The alleged support for the restriction requirement is stated by the Examiner in the final rejection as follows:

> "...the protein product as claimed can be made by other and materially different processes of making than by encoding the DNA of Claims 4-7, such as by other conventional purification techniques or combinations of other purification techniques including, ion exchange chromatography, hydrophobic interaction chromatography, thiophilic [sic] adsorption chromatography, immunoaffinity purification techniques, ultrafiltration, density gradient ultracentrifugation, reverse-phase HPLC and/or other conventional purification techniques. A product

made by other materially different processes of making is the requirement provided by the statute."

The aforesaid allegations by the Examiner concerning processes of making have no basis in fact and are drawn out of whole cloth as will be evident from the following analysis:

First of all, none of applicant's claims relate to a process or method of making. Thus, the Examiner's comments regarding "other and materially different processes of making" have no relevance to the claims. The present claims do not involve a situation in which one Group concerns a product and the other Group concerns a particular process or method of making under circumstances where other methods of making the product are known.

Secondly, it appears that the Examiner has done nothing more than recite a laundry list of conventional protein "purification" processes. The Examiner has not given any sufficient or valid reason whereby applicant's novel protein product can be "produced" or "made" by this laundry list of purification techniques.

Thirdly, although various "purification" techniques can be employed <u>after</u> applicant's protein is expressed by the DNA, there is absolutely no basis to the Examiner's conclusion that the protein of the Group I invention can be "made" by a process involving said laundry list of "purification" techniques.

Fourthly, the Examiner's recitation of a laundry list of purification techniques appears to be taken from some treatise or text on protein purification techniques but there is no stated connection between any of this and applicant's novel protein

having the specific 168 resides recited in both the Group I and Group II claims. It is respectfully submitted that the Examiner's listing thus constitutes nothing more than an arbitrary listing of a jumble of protein techniques without any adequate or sufficient reasons that support applicability to applicant's Group I and Group II product claims as required by the provisions of MPEP §803.

C. TO EXAMINE BOTH GROUPS I AND II IN THE PRESENT APPLICATION WOULD NOT CONSTITUTE A SERIOUS BURDEN ON THE EXAMINER AS SPECIFIED BY MPEP §803

Under the provisions of MPEP §803 restriction is not proper when there is no serious burden on the Examiner if the restriction is not required.

It is clear from the Examiner's examination of the provisionally elected Group II claims that there would be no serious burden on the Examiner to withdraw the restriction requirement and to also examine the Group I claims. Thus, it should be noted that although the Group II claims relate to "DNA" sequences, the Examiner has not cited any art which describes similar or related DNA sequences; instead, the Examiner has cited art which describes "proteins." That is, the Examiner in the alleged examination of the Group II claims has searched and found art which appear to be related to the Group I protein claims rather than the Group II DNA claims. Under such circumstances it would constitute an absurd and bizarre conclusion not to also examine the Group I claims at the same time. Thus, it is seen

that in the examination of the Group II claims the Examiner has cited the following two primary references:

Rauvala, EMBO J. 8, 2933-2941 (1989); and

Bohlen, EP 326,075.

A careful review of Rauvala will reveal that it describes an 18 kDa protein having a specific 14 amino acid residue NH_2-terminal sequence as set forth on page 2934, left hand column, penultimate paragraph. There is not one word within the four corners of the reference concerning a DNA sequence. Thus, it is apparent that this reference cited by the Examiner was found in the "protein" art which relates to the unexamined Group I claims rather than the "DNA" art which relates to the allegedly examined Group II claims.

Likewise, a careful review of Bohlen will reveal that it describes three proteins of, respectively, 18, 16 and 15 kDa molecular weight having corresponding amino acid residues as set forth in Table I on page 9. There is not one word within the four corners of the reference concerning a DNA sequence. Thus, it is apparent that this reference cited by the Examiner also was found in the "protein" art which relates to the unexamined Group I protein claims rather than the "DNA" art which relates to the allegedly examined Group II DNA claims.

Clearly then, the Examiner has cited two primary references drawn from "protein" art which constitute the most relevant art applicable to the Group I claims. As stated, above, it would constitute an absurd and bizarre conclusion not to examine the Group I claims under such circumstances. It is thus evident that the Examiner has searched the art applicable to the non-elected

Group I claims rather than the art applicable to the provisionally elected Group II DNA claims. Under such circumstances it would be no serious burden upon the Examiner to withdraw the restriction requirement and to examine the Group I claims in the present application. No such burden has been shown or justified such as required by MPEP §803.

Although the secondary reference, Maniatis, cited in the examination of the Group II claims relates to DNA sequences, it is nothing more than a state-of-the art manual of laboratory technique. It contains not the slightest hint concerning either applicant's DNA sequence or the protein encoded by the DNA sequence. It does not even describe DNA sequences of any related or analogous proteins. It has nothing whatsoever to do with applicant's protein and DNA product claims. Most certainly it provides no support to the requirement for restriction.

D. THE RESTRICTION REQUIREMENT PLACES AN UNREASONABLE AND UNNECESSARY BURDEN ON APPLICANT AND THE PUBLIC

To require restriction as between the Group I "protein" claims and the Group II "DNA" claims would constitute an unnecessary, unreasonable and burdensome requirement upon applicant and the public and would serve no useful benefit to the PTO. Since the DNA sequences of the Group II Claims 4-7 encode the protein sequences of the Group I Claims 1-3, it would be most convenient, efficient and logical, and would result in a savings of cost and time to both applicant and the PTO to have the two Group I and Group II claims examined in one application. According to common knowledge the PTO already is burdened with a

backlog of numerous applications in the biotechnology area. To divide this application of such closely related claims into two applications as would be necessitated by the restriction requirement, would result in a consequent duplication of effort and creation of excessive paperwork and a further backlog of prosecution. The cost to applicant in additional filing fees alone would be exorbitant, to say nothing of the additional cost of prosection. It would be necessary to create two patent file wrappers where only one should be necessary. Applicant has pointed out in Part C, above, that the Examiner has already cited the most relevant art applicable to the protein claims of Group I but cited nothing relevant to the DNA claims of Group II. Thus, it would constitute nothing more than a superfluous and unnecessary redundancy of effort to require examination of the Group I claims in a divisional application.

So also, the restriction requirement would constitute an unnecessary burden on the general public and scientists who are interested in the claimed technology. Thus, it is manifestly clear that the Group II claims do not relate to some random DNA sequences or nonsense sequences which have no meaning but, instead, they relate to DNA sequences that encode the specific protein sequences of the Group I claims. Any scientist who is concerned with or interested in the claimed DNA sequences of Group II most certainly would be interested in said sequences not because of some peculiar randomness or nonsense but, rather, because they encode and are intimately and inextricably related to the specific protein sequences of the Group I claims. Thus, if this application had to be split up into two applications, the public and interested scientists would have to search two patent file wrappers instead of one patent file wrapper for the patent examination results on DNA and protein sequences that are

intimately and inextricably related to each other. The public would gain nothing by upholding the restriction requirement.

Accordingly, it is respectfully submitted that the restriction requirement does not satisfy the provisions of MPEP §803 and should be reversed.

In view of the foregoing, favorable action on this petition is respectfully solicited.

Respectfully submitted,

By _____
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November 15, 1991

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IN RE APPLICATION:

THOMAS F. DEUEL, YUE-SHENG LI,

NED R. SIEGEL AND PETER G. MILNER

SERIAL NO.: 07/542,232

FILED: June 21, 1990

TITLE: HEPARIN-BINDING GROWTH FACTOR

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